EXHIBIT A

UNITED STATES DISTRICT COURT

DISTRICT OF MINNESOTA

THE TRUSTEES OF THE WELFARE AND PENSION FUNDS OF LOCAL 464A – PENSION FUND, et al., Individually and on Behalf of All Others Similarly Situated, Plaintiffs, vs. MEDTRONIC PLC, et al., Defendants.	Civ. No. 0:22-cv-02197-KMM-JFD CLASS ACTION DECLARATION OF PHILIP T. LAVIN, PH.D. IN SUPPORT OF PLAINTIFF'S MOTION FOR LEAVE TO FILE A FIRST AMENDED COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS

I, PHILIP T. LAVIN, PH.D., declare as follows:

1. I have been asked by Robbins Geller Rudman & Dowd LLP to evaluate Medtronic's submission for FDA approval of the MiniMed 780G insulin pump; the FDA's inspection of Medtronic's diabetes business headquarters in Northridge, California; the July 7, 2021 Form 483; and Medtronic's correspondence to the FDA following receipt of the Form 483. I have also been asked to evaluate the significance of items identified by the FDA on Form 483. The following is based upon evaluation of the relevant documents and sources discussed herein, my education, and my decades of relevant training and experience. Appended hereto is my curriculum vitae.

2. I am currently the Principal of a Boston-based biostatistics consulting practice, Lavin Consulting LLC, in business for 12 years, Executive Director for a not-for-profit research foundation, Boston Biostatistics Research Foundation, in business for 36 years, and co-founder of Melior Capital Management. In 1983, I founded and served as CEO for Boston Biostatistics, Inc., which became Averion in 2001, which grew into Averion International in 2006, which, upon a merger, became Aptiv Solutions in 2011, and which was purchased by ICON plc in 2014.

3. I received my Ph.D. in Applied Mathematics from Brown University in 1972. I have over 50 years of experience in the field of biostatistics as a: (1) faculty member at Brown University (2 years), Harvard School of Public Health (7 years), and Harvard Medical School (21 more years); (2) an FDA Advisory panel member and Special Government Employee (33 years); and (3) an expert consultant to the pharmaceutical, biotechnology, and medical device industries (50 years). I have authored or co-authored

>200 peer-reviewed publications. As relevant here, my work has contributed to the approval or clearance of 81 FDA-regulated products to date through Premarket Approvals (PMAs), New Drug Applications (NDAs), Biologic License Applications (BLAs), 510(k) de novos, as we well as a Humanitarian Device Exemption (HDE).

4. I am the only person to be an elected Fellow of both the Regulatory Affairs Professional Society and the American Statistical Association.

5. During my career, I have attended FDA meetings to discuss topics similar to the FDA's observations made during its inspection of the Northridge facility. An example would be the Gliatech AIP concerning its adhesion barrier medical device. I have attended >150 FDA meetings concerning medical devices between 1983 and 2015 when I served as a Special Government Employee. I additionally reviewed regulatory submissions, regulatory policies, and served on multiple FDA advisory panels.

6. Medtronic sought FDA approval for its next-generation insulin pump – the MiniMed 780G device – by submitting a "PMA supplement" to the "original PMA" for the MiniMed 670G device.[1] The FDA permits PMA supplements to be used in lieu of a new, standalone PMA when a medical device company wishes to update a device that has already obtained FDA approval. Relevant regulations provide that "[a]fter FDA's approval of a PMA, an applicant shall submit a PMA supplement for review and approval by FDA before making a change affecting the safety or effectiveness of the device for which the

[1] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160017S091 (demonstrating that the MiniMed 780G was submitted for approval pursuant to a "PMA supplement" to the linked "original PMA." The "original PMA" link takes the user to the MiniMed 670G PMA).

applicant has an approved PMA[.]"[2] The regulations provide that changes for which a PMA supplement may be used include, among others, "[n]ew indications for use of the device," "[l]abeling changes," and "[c]hanges in packaging."[3]

7. In this case, the PMA supplement for the MiniMed 780G device sought "modifications to the SmartGuard Technology and for expanding the indications for use to include the Guardian 4 Sensor."[4] Medtronic indicated in the Summary of Safety and Effectiveness Data that the MiniMed 780G PMA supplement "was submitted to introduce the MiniMed 780G System, which updates the pump control algorithm from the Hybrid Closed Loop (HCL) algorithm to the Advanced Hybrid Closed Loop (AHCL) algorithm and to add compatibility to the new Guardian 4 Continuous Glucose Monitor (CGM) as an alternative CGM component for the system."[5]

8. I understand that the MiniMed 670G device suffered from a defect related to the retainer ring used to lock together the pump and insulin cartridge, which resulted in the receipt of more than 74,000 complaints between June 2016 and November 2019. I understand that in November 2019 Medtronic issued a "Field Safety Notification" directing users of two models of MiniMed 600 Series pumps to examine their pumps' retainer ring and notify Medtronic if the ring appeared damaged or missing. I further understand that the FDA classified the Field Safety Notification as a Class I recall in February 2020 that

---

2 21 C.F.R. §814.39.

3 *Id.*

4 https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160017S091

5 https://www.accessdata.fda.gov/cdrh_docs/pdf16/P160017S091B.pdf

affected all four models of MiniMed 600 Series pumps. I understand that the FDA inspected Medtronic's Northridge facility – which was the headquarters for Medtronic's diabetes business that was responsible for both the MiniMed 670G and 780G devices – between June 7 and July 7, 2021. I understand that the FDA identified three categories of facility- and process-based deficiencies relating to Medtronic's ability to correct, prevent, investigate, and document the MiniMed 670G defects, which it described in a Form 483, dated July 7, 2021 (discussed below).

9. A Class I recall of a device is one that applies to "a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death."[6] Following a Class I recall related to a device, the FDA routinely conducts inspections of the facility or facilities responsible for manufacturing and monitoring the device to determine the cause(s) of the defect, assess whether the defect has been remedied, and assess the adequacy of the facility's processes and procedures meant to detect, address, and remedy product quality issues.[7] Consistent with this fact, following the Class I recall related to the defective retainer ring, the FDA

---

[6] https://www.fda.gov/medical-devices/postmarket-requirements-devices/recalls-corrections-and-removals-devices

[7] Federal regulations permit FDA inspectors "to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, tobacco products, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce . . ." *See* 21 U.S.C. §374. Inspections of establishments where devices are made "shall extend to all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether . . . devices . . . which are adulterated or misbranded within the meaning of this chapter . . . or have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violation of this chapter." *Id.*

inspected Medtronic's diabetes facility in Northridge, California between June 7 and July 7, 2021. On July 7, 2021, the FDA presented the findings of its inspection to Medtronic on a Form 483.

10. A Form 483, issued at the conclusion of an FDA inspection, is an inspection report established by federal statute.[8] Among other things specific to device hardware and software malfunctions, it can also include findings which reflect Good Clinical Practice (GCP) compliance issues, Standard Operating Procedures (SOP) violations, and insufficient documentation. The Form 483 must be presented to the owner, operator, or agent in charge of the inspected facility and it must include the observations of conditions or practices which, in the FDA inspector's judgment, indicate that a device "may have been rendered injurious to health."[9]

11. The July 7, 2021 Form 483 identified three broad categories of systemic, facility-level deficiencies that impacted the processes and safety controls (or lack thereof) at the Northridge facility, as follows:

(a) "Procedures for corrective and preventative action have not been adequately established."

(b) "Complaints involving the possible failure of a device to meet any of its specifications were not investigated where necessary."

---

[8] *See* 21 U.S.C. §374(b).

[9] *Id.*

(c) "Written MDR [Medical Device Report] procedures have not been implemented."

12. The Form 483's first finding – that the Northridge facility failed to establish "[p]rocedures for corrective and preventative action" – related to the facility's failure to "accurately calculate the risk associated with the failed retainer rings." The FDA found that the facility's risk classification assessments "resulted in underestimation of the Occurrence of harm . . ." The Form 483 continued, "all of these assessments used the same underestimated calculation for probability of occurrence and concluded again that the risk remained in Zone [redacted] even after a significant increase in complaints." Further, "the probability of occurrence has been underreported because the current calculation uses the '[redacted] of Affected Product' [redacted] instead of the number of products actually in the field ([redacted]). By using the number of products [redacted] your firm is including devices that are not in use by patients, thereby under-estimating the probability of occurrence." The Form 483 also determined that the Northridge facility "failed to implement a field action in a timely manner, to prevent patient deaths and serious injuries" and failed to timely effect a recall of the MiniMed 600 Series pumps, noting that although the company sent notifications regarding the defective pumps, "Technical Support personnel were instructed to tell customers that this field action was not a recall." "Technical Support personnel were also instructed to not replace defective pumps that were outside the warranty period." The Form 483 further noted that the facility "continues to receive reports of failures with the re-designed black retainer rings." Finally, related to the first finding, the Form 483 noted "a cyber-security vulnerability" with the MiniMed 508

insulin pumps and the MiniMed Paradigm insulin pumps "whereby an unauthorized user could hack the pumps [redacted]." "An evaluation of 'Cyber-Risk of Patient Harm' concluded that the [redacted] vulnerability due to lack of encryption could result in catastrophic harm to patients and classified the risk as '[redacted]' risk requiring remediation." However, Medtronic "failed to address the root cause of the vulnerability," "did not implement any corrective actions to address this vulnerability of the affected pumps," and "failed to conduct an effective recall."

13. The Form 483's second finding – that "[c]omplaints involving the possible failure of a device to meet any of its specifications were not investigated where necessary" – concerned the facility's failure to investigate complaints following the purported remedied retainer ring (the new, black retainer ring), which "may suggest that the corrective action (ring material change) may have not been effective." The Form 483 noted that the facility "confirmed the failures [with the new retainer ring], but no formal investigation was initiated." The facility also received a complaint of a patient receiving un-programmed boluses of insulin, yet the facility "failed to review the actual pump history to verify the boluses reported by the patient." Additionally, the facility received a report of a patient experiencing multiple pump sensor failures, yet the facility "did not analyze the defective sensors[.]" Further, the facility received a report of a frozen display screen, which, per the "Risk Analysis Document," posed "the risk of the pump user interface becoming unresponsive and the patient not being able to stop or start insulin delivery [which] could result in death (over delivery) or diabetic ketoacidosis (under delivery)."

Nevertheless, the facility did not use its available tools "to analyze the returned defective pump to ensure that a thorough investigation is conducted."

14. The Form 483's third finding – that "[w]ritten MDR procedures have not been implemented" – related to the facility's "fail[ure] to submit Medical Device Reports (MDRs) for [redacted] customer complaints . . . related to MiniMed 600 Series Insulin pump retainer ring failures where the returned product analysis confirmed that the reservoir was unable to lock into place."[10] "The rationale for not submitting the MDRs documented for [redacted] of these complaints was that the information does not suggest the malfunction would cause or contribute to a serious injury []; however, all of these complaints were received after the Field Product Impact Assessment [] concluded that the failure of the ring could potentially result in under delivery of insulin leading to hyperglycemia, severe hyperglycemia, or diabetic ketoacidosis; or over delivery of insulin leading to mild or severe hypoglycemia or death." Additionally, the facility "failed to submit [redacted] MDRs within [redacted] of becoming aware of information that

[10] "The Medical Device Reporting (MDR) Regulation requires medical device manufacturers, device user facilities and importers to establish a system that ensures the prompt identification, timely investigation, reporting, documentation, and filing of device-related death, serious injury, and malfunction information." *See* https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-guides/medical-device-reporting. "Mandatory reporters (that is, manufacturers, device user facilities, and importers) are required to submit to the FDA certain types of reports for adverse events and product problems about medical devices." *See* https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems#overview. "Medical Device Reporting (MDR) is one of the postmarket surveillance tools the FDA uses to monitor device performance, detect potential device-related safety issues, and contribute to benefit-risk assessments of these products." *Id.*

reasonably suggests that MiniMed Infusion pumps have malfunctioned and would be likely to cause or contribute to death or serious injury if the malfunction was to recur."

15. The three broad categories of systemic, facility-level deficiencies summarized above implicated the processes and safety controls (or lack thereof) at the Northridge facility. Unlike a lab that simply required more detailed cleaning or missing equipment servicing records, based on my knowledge and decades of relevant experience, these deficiencies were not easily or quickly fixed. Rather, these deficiencies implicated an entrenched lack of adequate safety and compliance procedures that were necessary to ensure that device defects and complaints arising from devices coming out of the Northridge facility were adequately investigated, remediated, and reported to the FDA. In my opinion, these systemic, pervasive deficiencies could not reasonably be remediated and cleared by the FDA in a matter of weeks or months. Rather, in my experience, these fundamental deficiencies, which implicated the Northridge facility as a whole, required protracted remediation efforts that could take a year or more to complete, document, and verify for effectiveness. This protracted process would include devising new risk models, securing and analyzing device-specific malfunctions from a universe of >57,000 MDR reports, establishing acceptable MDR reporting guidelines, presenting these efforts to the FDA, and obtaining assurance from the FDA that the efforts sufficiently remediated the previously identified deficiencies. I agree with Medtronic's acknowledgement in the

December 9, 2021 Warning Letter that the deficiencies first identified in the Form 483 required "extensive remediation."[11]

16. Because these deficiencies concerned facility-wide issues that implicated the Northridge facility's ability to monitor, remediate, and report product defects leading to potential severe patient injury and death, it is my opinion that FDA approval of the MiniMed 780G and any other new device coming out of the Northridge facility would be necessarily stalled from when those defects were identified by the FDA until the deficiencies were remediated, documented, and tested for effectiveness to the FDA's satisfaction.

17. I have also reviewed correspondence sent from Medtronic to the FDA following receipt of the Form 483 to confirm the above cited "extensive remediation." I understand that Medtronic sent at least five such letters:

(a) On July 28, 2021, Sean Salmon (Executive Vice President and President, Diabetes Operating Unit) and Chirag Tilara (Vice President, Quality) sent their first letter to the FDA, stating that "Medtronic is taking actions to address each of the three observations in the FDA-483, including actions related to our risk management system, complaint investigations, and Medical Device Report (MDR) accuracy and timeliness. In addition, Medtronic MiniMed has responded to two Management Discussion topics discussed during the closing meeting on July 7, as presented by the investigator." In light of the systemic deficiencies identified in the Form 483, the letter stated that "Medtronic

[11] During a January 10, 2022 healthcare conference, Medtronic CEO Geoffrey Martha stated that the facility deficiencies required "extensive remediation."

MiniMed is taking broad, systemic actions to improve the capability and rigor of our processes and execution." The letter attached an appendix describing "the actions that will be taken to address the observations," including "planned dates of completion for future actions." In the appendix, Medtronic stated that the facility planned to engage a "well-respected quality consulting organization, to conduct rigorous and thorough evaluations of the implementation and effectiveness of the actions identified in this Form-483 response" and would continue to conduct reviews "until all actions are fully implemented and verified effective." The appendix also identified numerous action items the facility planned to undertake to address the deficiencies, with estimated completion dates ranging from August 3, 2021 to January 31, 2022.

(b) On September 3, 2021, Sean Salmon and Chirag Tilara sent their second letter to the FDA, which was the facility's "first update to the initial response regarding the Form FDA-483 . . . that was submitted on July 28, 2021." It stated that "[a]ll remaining actions are on track for completion by the planned due dates." The appendix identified numerous action items the facility planned to undertake to address the deficiencies, with estimated completion dates ranging from September 10, 2021 to January 31, 2022.

(c) On October 8, 2021, Sean Salmon and Chirag Tilara sent their third letter to the FDA, which was the facility's "second update to the initial response regarding the Form FDA-483 . . . that was submitted on July 28, 2021." It stated that "[a]ll remaining actions are on track for completion by the planned due dates." The appendix identified numerous action items the facility planned to undertake to address the deficiencies, with

estimated completion dates ranging from October 15, 2021 to January 31, 2022. The appendix also referred to corrective actions related to "Complaint Investigations" that were incomplete and did not have an estimated completion date. Rather, the appendix stated that the corrective actions would be "managed through the CAPA [Corrective Action and Preventative Action] process" and purported to close the actions "for purposes of reporting to FDA."

(d) On November 5, 2021, Sean Salmon and Chirag Tilara sent their fourth letter to the FDA, which was the facility's "third update to the initial response regarding the Form FDA-483 . . . that was submitted on July 28, 2021." It stated that "[a]ll remaining actions are on track for completion by the planned due dates." The appendix identified numerous action items the facility planned to undertake to address the deficiencies, with estimated completion dates ranging from November 19, 2021 to June 24, 2022. The appendix also referred to remediation plans and complaint investigation corrective actions that were incomplete and did not have an estimated completion date. Rather, the appendix stated that the corrective actions would be "managed through the CAPA process" and purported to close the actions "for purposes of reporting to FDA."

(e) On December 3, 2021, Sean Salmon and Chirag Tilara sent their fifth letter to the FDA, which was the facility's "fourth update to the initial response regarding the Form FDA-483 . . . that was submitted on July 28, 2021." It stated that "[a]ll remaining actions are on track for completion by the planned due dates." The letter included a table with numerous outstanding items, but the "Expected Phase" column was fully redacted. The appendix identified numerous action items the facility planned to undertake to address

the deficiencies, with estimated completion dates ranging from January 28, 2022 to January 14, 2023. The appendix also referred to remediation plans and complaint investigation corrective actions that were incomplete and did not have an estimated completion date. Rather, the appendix stated that the corrective actions would be "managed through the CAPA process" and that "Medtronic MiniMed will provide updates on remediation activity on a periodic basis until remediation is complete."

18. Based on my experience, these letters reflected the extensive, prolonged remediation required by the systemic deficiencies identified in the Form 483. Sean Salmon and Chirag Tilara acknowledged in their July 28, 2021 letter that "broad, systemic actions" were required to address the deficiencies identified in the Form 483. Indeed, it took Medtronic three weeks to submit its first reply to the Form 483. From the outset, the July 28 letter identified extensive actions to address each of the three observations in the FDA 483 concerning the risk management systems, complaint investigations, and MDR accuracy and timeliness. For example, Table 1 to the July 28 letter identifies 23 initial action items to support the resolution of these three major issues. In my opinion, these are time consuming activities which, collectively, would take a year or more to complete, document, test for effectiveness, and present to the FDA, not including FDA feedback and time to sign off on completed tasks. The five major Medtronic-cited actions included:

(a) Proactive replacement of MiniMed 600 Series devices with a clear retainer ring in the United States. Medtronic proposed to prepare – but had not yet completed – a "detailed execution plan" at the first monthly update. This activity is tantamount to a product recall, which is a significant effort.

(b) Proactive retrieval of key fobs from active users of Paradigm systems who have received Paradigm remote key fobs since 1999. This also represents a product recall on the same track as the MiniMed 600 Series devices.

(c) Further risk management system refinements, including how to evaluate actions to better manage safety risk and how to ensure prompt, urgent attention when evaluating potential actions including supplemental independent evaluation. Risk management refinements of this nature take significant time to implement and to assess plan success.

(d) Further implementation of systemic improvements throughout the complaint handling, complaint investigation, MDR reporting, and CAPA processes. To leverage best practices and independent subject matter expertise, Medtronic planned to deploy resources and experts from other business divisions as well as hire additional resources. This, too, requires significant time to implement and to gauge plan success.

(e) Last, Medtronic planned to hire an outside quality consulting organization to conduct rigorous and thorough evaluations of the implementation and effectiveness of the remediation plans identified in July 28 letter. This also takes significant time to implement solutions and introduced the potential that additional deficiencies would be uncovered.

19. Moreover, as time went on and Medtronic continued to send its second, third, fourth, and fifth update letters, many deficiencies remained with estimated completion dates spanning well into 2022 and 2023 or with no estimated completion date at all. Putting aside what were in my opinion optimistic estimated completion dates, even if Medtronic

had succeeded in completing some or all of the required remediation by their estimated dates, it would take many months after completion for the FDA to review the remediation efforts, review the voluminous documentation describing the efforts, and verify that the corrective actions were effective. Notably, I am aware of no evidence showing that between the July 7, 2021 Form 483 and the final letter from Medtronic dated December 3, 2021 that the FDA agreed that any of Medtronic's remediation efforts were effective.

20. On December 9, 2021, the FDA issued a Warning Letter to Medtronic arising from the deficiencies identified in the Form 483. Consistent with my understanding of the protracted nature of the remediation required by the deficiencies presented in the Form 483, the Warning Letter cited the Northridge facility's failure to provide "evidence of implementation for all corrections and corrective actions" and stated, "your corrective actions are still in process, and you have not yet conducted effectiveness checks to ensure the updated procedures and required employee training will prevent reoccurrence of the identified deficiencies." Further, the Warning Letter stated, "as part of your corrective actions are not yet complete, including your retrospective complaint review and systemic complaint investigation processes and training, we cannot evaluate the adequacy of your response at this time." Reflecting the reality that the deficiencies would not be cleared until the corrective actions were completed and determined to be effective, the Warning Letter stated that although the facility committed to implement a new training program, "you also report that training of personnel will not be complete until [redacted]." Similarly, relating to a proposed new risk management plan, the Warning Letter stated, "[i]t is unclear if this plan incorporates an adequate risk analysis . . . and you state that your planned actions

will not be complete until [redacted]." Because items were "still in progress," the FDA, as expected, declined to clear the deficiencies. The Warning Letter's determination is consistent with my opinion that the facility- and process-based deficiencies identified in the Form 483 would take at least a year, if not longer, to complete, assess, and verify for effectiveness. Notably, the FDA did not lift the Warning Letter until April 2023.[12]

I declare under penalty of perjury that the foregoing is true and correct. Executed on 26 April 2024, at London, United Kingdom.

PHILIP T. LAVIN, PH.D.

[12] On April 25, 2023, the FDA sent a letter to Geoffrey Martha stating that "it appears that you have addressed the violation(s) contained in the Warning Letter." *See* https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/medtronic-minimed-inc-617539-04252023.

Name: **PHILIP T. LAVIN**

Industry Experience:

Summary: 50 years in clinical trials serving as an expert biostatistician, strategist, and regulatory consultant

2013 – Present	Principal Lavin Consulting LLC
1988 – Present	Founder and Executive Director Boston Biostatistics Research Foundation Inc.
2019 – Present	Co-founder Melior Capital Management

Current responsibilities include:

Senior biostatistics (strategic planning, study design, endpoint construction, modeling, analysis, and representation), regulatory strategy (agency interaction and presentation), helping sponsors secure approval for drugs, biologics, and devices and reimbursement leading to 82 regulatory approvals and clearances (43 PMAs/CE Marks, 23 NDAs, 4 BLAs, 2 de novos, 1 HDE, 9 510k clearances) and one GRAS petition.

2011 – 2013	Executive Vice President, Strategic Planning and Innovation Center Aptiv Solutions
2007 – 2011	Executive Chairman and Vice Chairman of the Board Averion International
1983 – 2007	Founder and CEO Averion International (formerly Boston Biostatistics Inc.)
1983 – 2015	Special Government Employee FDA

Past responsibilities included:

Executive management, strategic management, regulatory strategy, biostatistics, proposals, presentations, publications, and collaborations in pre-clinical studies, clinical trials, post-market approvals, and innovative modeling approaches for study design, longitudinal modeling, meta and mega analyses, epidemiology, cost-benefit modeling, and health care reimbursement, while serving as an FDA advisor and panel member for drugs, devices, and biologics.

Statistical and Regulatory Contributions:

1. The quasi-non-inferiority design for reducing sample size in randomized clinical trials by assuming that the innovator device has some advantage rather than no advantage
2. The use of composite endpoints for clinical trial powering and effectiveness demonstration
3. The concept of multi-dimensional efficacy for single pivotal studies in support of registration
4. The use of hierarchical testing sequence to preserve Type I error to extend labeling claims
5. The use of longitudinal modeling in interim analyses to maximize information available for decision making whether to stop, continue, or expand a clinical trial

6. The minimal alpha spending for blinded interim looks to re-estimate sample size
7. The concept of sensitivity, specificity, and lead time for biomarkers and companion diagnostics
8. The importance of using the same formulas to compute power and statistical significance
9. The use of prospective statistical analysis plans to pre-define populations, endpoints, and analysis methods prior to database lock to control Type I error
10. The exclusion of non-treatment related deaths and progressions from serious adverse event counts in oncology studies
11. The use of computer-generated edit checks to clean data prior to database lock.

Academic Experience:

1989 – 2005	Adjunct Associate Professor, Clinical Associate Professor Harvard Medical School, Boston, MA 02115
1983 – 1989	Associate Professor Harvard School of Public Health Boston, MA 02115
1977 - 1983	Assistant Professor Harvard School of Public Health Boston, MA 02115
1974 - 1977	Research Assistant Professor, Statistical Laboratory, Statistical Science Division, SUNY at Buffalo, Buffalo NY
1972 – 1974	Assistant Professor of Research, Division of Applied Mathematics, Brown University, Providence RI

Responsibilities included:

Teaching, research, cooperative group (ECOG, GITSG) collaborations, and publications

Education:	Brown University, Providence RI PhD, Applied Mathematics (Statistics), 1972
	University of Rochester, Rochester NY (Summa Cum Laude) AB, Mathematics, 1968
Patents:	System and Method for Diagnostic Vector Classification Support (to differentiate between benign and malignant breast masses based on three internal and two external features using statistical algorithms); Patent # 9,398,893 issued July 26, 2016
	System and Method for Diagnostic Vector Classification Support; Patent # 10,026,170 issued July 17, 2018

Presentations:

2016	AHA Frontiers in Stem Cells Research: Statistical Considerations FDA Industry Workshop: Writing Statistical Contracts
2015	SOCRA: The Statistics Behind Risk Based Monitoring MDIC: Optimizing Medical Device Study Designs FDA Industry Workshop: Statistical IP Considerations

	SABCS: Breast Cancer Detection Algorithms
2014	SABCS: Nomogram for Breast Cancer Diagnosis RAPS: Adaptive Designs for Regulatory Submissions
2013	AIUM: Opto-acoustics for Breast Cancer Detection RAPS: Maximizing Good Relationships with Regulatory Agencies
2012	Q1 Productions: Planning and Executing Adaptive Designs Q1 Productions: Statistical Strategies for Medical Device Studies
2011	Q1 Productions: Statistical Strategies for Medical Device Studies IBC: Reimbursement Planning Strategies using Phase 3 Data
2010	IBC: Adaptive Designs for Biologics and Drugs
2009	IBC: Statistical Designs for Biomarkers
2008	JSM: Quasi-non-inferiority Designs for Medical Devices
2007	Mass BioTech Council: "Statistical Challenges Supporting DMCs" Neonatology Summit: "Mortality and LOS Modeling Issues Comparing Surfactants" American Statistical Association: "Designing Quasi-superior Device Studies"
2006	American Statistical Association: "Common Themes in Medical Device Studies"

Litigation Support:

45 cases (plaintiffs and defendants)
36 reports (torts, patent infringement, claims, contract disputes, false and misleading statements)
29 depositions (clinical trials, biostatistics, regulatory, science)
4 court appearances (very low calorie diets, knee implants, oncology)

FDA/EMA Approvals and Clearance/Clinical Trials Experience:

Drugs
(23 NDA approvals):

Acid Reflux (Axid)
Acne (Estrostep, Azelex)
AIDS (Foscavir)
Anemia (Fereheme)
ARDS
Asthma (Albuterol)
Bipolar disorder
COVID-19
Cystic Fibrosis (ZenPep)
Cushing Syndrome
Depression
Diabetes
Endometriosis
Epilepsy
Frederich's Ataxia
Gastric Ulcers
Glaucoma
Hepatology
Hyperlipids (Cholestagel)
Hyperkalemia (Lokelma)
Hypertension
Infection (Ceftobiprole)
Lipidemia (Lipitor)
Macular Edema
Motion Sickness (Refaximin)
Multiple Sclerosis
Obesity
Oncology (Adriamycin)
Oncology: GI (Erbitux), Lung, Brain, H&N, Ovarian
Onychomycosis
Ophthalmology (Glaucoma, Macular Disease, Dry Eye)
Osteo-arthritis (Flurbiprofen)
Pain Control (Dyloject, Nasal Morphine, Ketamine)
Pain Relief (EMLA)
Pulmonary: COPD
Renal (Renagel)
Rosacea (Finacea)
Substance Abuse (Naltrexone, Nalbuphine)
Suicide Prevention
Urinary Incontinence

Biologics
(4 BLA approvals):

Burns
COVID-19
Decubitis Ulcers
Gum Disease (GINTUIT)
Hepatitis B and C
Huntington's Disease
Liver Assist Device
Melanoma (OncoVex)
Multiple Sclerosis
Oncology (ONTAK)
Psoriasis
Renal Assist Device
Rheumatoid Arthritis
Sepsis
Transplants
Vaccines (OspA)
Wound Healing

GRAS (1 approval)

Enteral Nutrition (IMPACT)

Devices (43 PMAs/CE Marks, 2 de novos, 1 HDE approvals, 9 510k clearances):

Adhesion Prevention (ADCON-L)
Angina (TMR)
Angiography (SPY-PHI)
Ankle Healing (Augment)
Artificial Organs: Heart, Kidney, Liver
Biomarkers (CA-125, PSA, sIL2r)
Breast Cancer Imaging (Imagio)
Cardiac Access (Crossing Solutions)
Cardiac Adhesions (REPEL-CV)
Catheter Lock Solution (Zuragen)
Cervical Disc (Mobi-C [1,2], ProDISC-C [1,2])
Cervical Dysplasia Detection (LUNA, DysisMap)
Colorectal Cancer Screening (ColoGuard)
Connective Tissue (Orthogold 100)
Cryoablation (FROSSTY)
Dermal Filler (RADIESSE)
Diabetes: Glucose Monitoring
Dialysis (Zuragen)
Fat/Flanks Reduction (eon FR)
Femoral Artery Closure (VCD [3])
Finger Implant (PCP)
Fracture Healing (SAFHS)
Hearing Aid (Naída CI M processor/software)
Hip Implant (C/C)
Imaging: US, CT, OA (Imagio)
Knee: Cartilage repair and regeneration
Knee OA IA (OrthoVisc, Synvisc, SUPARTZ, Gel-One, Monovisc, GenVisc850, Hymovis)
Lumbar Disc (ProDISC [1,2])
Metastatic Pain Relief (Quadramet)
Neurologic Vessel Repair (LVIS, WEB, FRED)
Neurological Impulses (NC-Stat)
Ophthalmology (DR [IDx])
Osteoporosis Detection (SAHARA)
Periodontal Regeneration (GEM 21S)
Peripheral Crossing System (SoundBite)
Rib Spacer (VEPTR)
Sacral Implants (SI-BONE)
Shoulder (InSpace)
Spinal Fusion Cage (BAK)
Spinal Stimulation (Neuros E-P)
Ulcers: Decubitis, Venous Stasis
Urinary Incontinence (Stress, Urge, Mixed)
Wound Healing (APLIGRAF)

Research Expertise:

Clinical:	Applications:	Methodology:
Biomarkers	Multiple endpoints	Adaptive design
505(b)2	Multiple comparisons	Sequential analysis
Bioequivalence	Composite endpoints	Longitudinal modeling
Biosimilars	Artificial intelligence	Simulations
Devices	Multi-study modeling	Exact inference
Drugs	Cost-benefit modeling	Prediction
Combination Products	Optimization models	Survival analyses
Imaging	Instrument validation	Time series
Biologics	Meta analyses	Markov processes
Quality of Life	Cost reimbursement	Bayes modeling
Companion Diagnostics	Adaptive modeling	Interim analyses
Vaccines	Registries	Survey sampling
Veterinary Products	Predictive models	Epidemiology
Pharmacovigilance	Sample size models	Classification
		Missing at random

Technical Experience:

Software: MS Word, PowerPoint, Excel, StatXact, nQuery, EaSt, ADDPLAN

Honors/Awards:

2009	RAPS Fellow
2008	ASA Fellow
2007	Earl Robinson Award, The American Society of Periodontology
2007-	Who's Who in the World
2006	Earl Robinson Award, The American Society of Periodontology
2000	The American Society of Reproductive Surgery
1999 -	Who's Who in America
1985 -	Who's Who in International Medicine
1984 -	Who's Who in Cancer Research
1981 -	Who's Who in Technology Today
1976 -	Who's Who in American Men of Science
1968 - 1972	National Science Foundation (NSF) Fellowship
1968	Phi Beta Kappa

Public Service:

1987 – 1993	NASCO, Continuing Education
1986 – 1997	Statistical Editor, Antimicrobial Agents and Chemotherapy
1986 – 1989	Editorial Board, Drug Information Association (DIA)
1983 - 2015	FDA Special Government Employee
1981 – 1999	NIH Grants and Contracts Reviewer

Affiliations/Memberships:

2013-	American Society of Nephrology
2012-	World Molecular Imaging Society

1986- Regulatory Affairs Professional Society
1984- Drug Information Association
1979- Biometrics Society
1976- American Statistical Association

Publications

ORIGINAL ARTICLES

1. Douglass HO, Jr., Lavin PT. A Study of Nitrosourea Toxicity in Gastrointestinal Protocols of the Eastern Cooperative Oncology Group, Cancer Treatment Reports, 60:769-780, 1976.

2. Schein P, Lavin P, et al for the Gastrointestinal Tumor Study Group, Randomized Phase II Clinical Trial of Adriamycin, Methotrexate, and Actinomycin D, in Advanced Measurable Pancreas Carcinoma, Cancer, 42:19-22, 1978.

3. Falkson G, Moertel C, Lavin P, for the Eastern Cooperative Oncology Group, Chemotherapy Studies in Primary Liver Cancer, A Prospective Randomized Clinical Trial, Cancer, 42:2149-2156, 1978.

4. Douglass HO, Jr., Lavin PT, et al. for the Eastern Cooperative Oncology Group, Chemotherapy of Advanced Measurable Colorectal Cancer, Cancer, 42:2538-2545, 1978.

5. Carbone PP, Davis TE, Zelen M, Lavin P, Eastern Cooperative Oncology Group - Progress Report of Activities and Plans, Cancer Clinical Trials, 1:65-75, 1978.

6. Schapira D, Hall T, Bennett J, Lavin P, Schnider B, for the Eastern Cooperative Oncology Group, A Phase II Study in Estradiol Mustard, Cancer Clinical Trials, 1:5-8, 1978.

7. Chu, TM, Lavin P, Day J, Evans J, Mittelman, A, Holyoke, E, Vincent, R, Carcino-Embryonic Antigen: Prognosis and Monitoring of Cancer, Carcino-Embryonic Proteins, Vol. I, Elsevier/North Holland Biomedical Press, 1979.

8. Lokich J, Lavin P, Moertel C, et al, for the Gastrointestinal Tumor Study Group, A Multi-Institutional Comparative Trial of Radiation Therapy Alone and in Combination with 5-Fluorouracil for Locally Unresectable Pancreatic Carcinoma, Annals of Surgery, 189:205-208, 1979.

9. Moertel CG, Engstrom P, Lavin PT, Gelber R, Carbone P, for the Eastern Cooperative Oncology Group, An Evaluation of 5-FU, Lactones, and Nitrosoureas in Patients with Advanced Non-Measurable Gastric and Pancreas Cancer, Journal of Surgery, 85:509-513, 1979.

10. Douglass HO, Lavin PT, Evans J.T, Mittelman A, Carbone PP, Phase II Evaluation of Diglycoaldehyde, VP-16-213, and the combination of Methyl-CCNU and Beta-2'-Deoxythioguanosine in Previously Treated Patients with Colorectal Cancer: An Eastern Cooperative Oncology Group Study (EST-1275), Cancer, 63:1355-1357, 1979.

11. Lavin P, Holyoke D, Zamcheck N, for the Gastrointestinal Tumor Study Group, A CEA Standardization Experiment for the Conduct of Multi-institutional Trials, Cancer Treatment Reports, 63:2031-2033, 1979

12. Moertel CG, Lavin PT, for the Eastern Cooperative Oncology Group, Phase II-III Chemotherapy Studies in Advanced Gastric Cancer, Cancer Treatment Reports, 63:1863-1869, 1979.

13. Lavin PT, and Moertel CG, for the Gastrointestinal Tumor Study Group, Phase II-III Chemotherapy Studies in Advanced Gastric Cancer, Cancer Treatment Reports, 63:1871-1876, 1979.

14. Lokich JJ, Childs DS, Kalser M.H, Lavin PT, Douglass HO, et al, for the Gastrointestinal Tumor Study Group: Comparative therapeutic trial of radiation with or without chemotherapy in pancreatic carcinoma, Int J Radiat Oncol Biol Phys 5:1643-1647, 1979.

15. Lavin PT, and Flowerdew G, Studies in Variation Associated with the Measurement of Solid Tumors, Cancer, 46:1286-1290, 1980.

16. Lavin PT, Mittelman A, Douglass H, Engstrom P, Klaassen D, Survival and Response to Chemotherapy of Colorectal Adenocarcinoma, Cancer, 46:1536-1543, 1980.

17. DeWys W, Begg C, Lavin PT, et al, for the Eastern Cooperative Oncology Group, Prognostic Effect of Weight Loss Prior to Chemotherapy in Cancer Patients, American Journal of Medicine, 69:491-497, 1980.

18. Macdonald JS, Schein PS, Woolley PV, Smythe T, Ueno W, Hoth D, Lavin P. 5-Fluorouracil, doxorubicin, and mitomycin (FAM) combination chemotherapy for advanced gastric cancer Annals Internal Medicine 93 (4), 533-536, 1980.

19. Kinsella TJ, Bloomer W.D, Lavin PT, Knapp RC, Stage II Endometrial Carcinoma: 10 Year Followup of Combined Radiation and Surgical Treatment, Gynecologic Oncology, 10:290-297, 1980.

20. Falkson G, Moertel C, MacIntyre J, Lavin P, Engstrom P, Carbone P, The Value of Cytostatic Agents in the Treatment of Patients with Primary Liver Cancer, Diagnosis and Treatment of Upper Gastrointestinal Tumors, International Congress Series No. 542, 455-459, 1980.

21. Osband M, Lipton J, Lavin P, Levey R, Vawter G, Greenberger J, McCaffrey R, Parkman R, Histiocytosis-X: Demonstration of Autoimmunity, Suppressor Cell Deficiency and Successful Treatment with Thymic Extract, New England Journal of Medicine, 304:146-153, 1981.

22. Lavin P, Day J, Holyoke ED, Mittelman A, Chu TM, An Evaluation of Baseline and Followup CEA in Patients Undergoing Resection for Cure for Colorectal Carcinoma, Cancer, 47:823-826, 1981.

23. Osband M, Shen Y, Shlesinger M, Lavin P, et al, Successful Tumor Immunotherapy with Cimetidine in Mice, Lancet, 1:636-638, 1981.

24. Wagoner M, Albert D, Lavin P, Corneal Donor Material Selection, Ophthalmology, 83:139-144, 1981.

25. Moertel C, Lavin PT, et al, for the Gastrointestinal Tumor Study Group, Therapy of Locally Unresectable Pancreatic Carcinoma: A Randomized Comparison of High Dose Radiation Along, Moderate Dose Radiation + 5-FU, and High Dose Radiation + 5-FU, Cancer, 48:1705-1710, 1981.

26. Lavin P, Alternative Measures of Anti-Tumor Activity in the Evaluation of Solid Tumors, Cancer Clinical Trials, 4:451-459, 1981.

27. Engstrom P, Lavin P, Douglass HO, Adjuvant Therapy of Gastric Carcinoma using 5-Fluorouracil and Semustine, European Journal of Cancer, 31-35, 1981.

28. PS Schein, Gastrointestinal Tumor Study Group. A comparison of combination chemotherapy and combined modality therapy for locally advanced gastric carcinoma. Cancer 49 (9), 1771-1777.

29. O'Fallon J, Lavin P, O'Connell M, Moertel C, et al, for the Gastrointestinal Tumor Study Group, A Comparative Clinical Assessment of Combination Chemotherapy in the Phase II-III Evaluation of Combination Therapy with Management of Advanced Gastric Cancer, Cancer, 49:1362-1366, 1982.

30. Karp DD, Ervin TJ, Tuttle S, Gorgone B, Lavin PT, Yunis E.J, Pulmonary Complications During Granulocyte Transfusions: Incidence and Clinical Features, Vox Sanguinis, 42:57-61, 1982.

31. Harmon W, Lavin P, Parkman R, Ingelfinger J, Grupe W, Levey R, The Correlation of Early Acute Rejection Episodes with Long-Term Renal Transplant Outcome, Transplantation, 33:648-649, 1982.

32. Bruckner H, Lavin P, Plaxe S, Storch JA, Livstone E, for the Gastrointestinal Tumor Study Group, Absolute Granulocyte, Lymphocyte, and Monocyte Counts. Useful Determinants of Prognosis for Patients with Metastatic Cancer of the Stomach, JAMA, 247:1004-1006, 1982.

33. Moertel CG, Lavin PT, Hahn G, Phase II Evaluation of Adriamycin in Islet Cell Carcinoma, Cancer Treatment Reports, 66:1567-1569, 1982.

34. Harmon W, Parkman R, Lavin P, Grupe W, Ingelfinger J, Yunis E, Levey R, Comparison of Cell Medicated Lympholysis and Mixed Lymphocyte Culture in the Immunological Evaluation for Renal Transplantation, Transplantation, 129, 4:1573-1577, 1982.

35. Lavin PT, Bruckner, H, Plaxe, S, Studies in Prognostic Factors Relating to Chemotherapy for Advanced Gastric Cancer, Cancer, 50:2016-2023, 1982.

36. Gonder JR, Shields JA, Albert DM, Augsburger JJ, Lavin PT, Uveal Malignant Melanoma Associated with Ocular and Oculodermal Melanocytosis, Ophthalmology, 89, 8:953-960, 1982.

37. Lavin PT, Structure Preserving Image Restoration, IEEE Pattern Analysis and Machine Intelligence, 5:14-24, 1983.

38. Bruckner H, Lavin P, Plaxe S, Storch JA, Livstone E, for the Gastrointestinal Tumor Study Group, Routine Clinical Chemistries as Improved Determinants of Prognosis for Patients with Metastatic Cancer of the Stomach, Oncology, 40:31-35, 1983.

39. Johnson LA, Lavin P, Moertel CG, et al, Carcinoids: The Association of Histologic Growth Pattern and Survival, Cancer, 51:882-889, 1983.

40. Bast RC, Reinherz EL, Mayer C, Lavin P, Schlossman SF, Contrasting Effects of Cyclophosphamide and Prednisolone on the Phenotype of Human Peripheral Blood Leukocytes, Clinical Immunology and Immunopathology, 28:101-114, 1983.

41. Lavin PT, Practical Considerations in the Coordination of Clinical Trials, in Issues in the Conduct of Clinical Trials, T. Louis and S. Shapiro (Eds.), Marcel Dekker, New York City, 129-153, 1983.

42. Albert D, Searl S, Lavin P, Uveal Findings in Patients with Cutaneous Melanoma, American Journal of Ophthalmology, 95:474-479, 1983.

43. Engstrom, PF, Lavin PT, Klaassen, DJ, Phase II Evaluation of Mitomycin and Cisplatin in Advanced Esophageal Carcinoma, Cancer Treatment Reports, 67, 7-8:713-715, 1983.

44. Albert DM, Searl SS, Forget B, Lavin PT, Kirkwood J, Nordlund JJ, Uveal profile in patients with cutaneous melanoma, Am J Ophthalmol. 95(4):474-479, 1983.

45. Ellsworth R, Javitt J, Abramson D, Haik B, and Lavin P: Cobalt plaque therapy for ocular melanoma. Ophthalmology 91suppl:98, 1984.

46. Seddon, J, Albert, D, Lavin P, A Prognostic Factor Study of Disease-Free Interval and Survival Following Enucleation for Uveal Melanoma, Archives of Ophthalmology, 101:1894-1899, 1983.

47. Lavin P, Albert, D, Seddon, J, A Deficit Survival Analysis to Assess the Natural History of Uveal Melanoma, Journal of Chronic Diseases, 37, 6:481-487, 1984.

48. Engstrom PF, Lavin PT, Moertel CG, Folsch E, Douglass HO, Jr., Streptozotocin plus Fluorouracil vs. Doxorubicin Therapy for Metastatic Carcinoid Tumor, Journal of Clinical Oncology, 2, 12:1255-1259, 1984.

49. Douglass HO, Lavin PT, Goudsmit A, Klaassen DJ, Paul AR, An Eastern Cooperative Oncology Group Evaluation of Combinations of Methyl-CCNU, Mitomycin C, Adriamycin and 5-Fluorourail in Advanced Measurable Gastric Cancer, Journal of Clinical Oncology, 2, 12:1372-1381, 1984.

50. Bast RC, Klug, TL Schaetzl E, Lavin PT, Niloff J, Greber, T Zurawski, V Knapp, R Monitoring Human Ovarian Carcinoma with a Combination of CA-125, CA19-9, and Carcinoembryonic Antigen, Obstetrics and Gynecology, 149, 5:553-9, 1984.

51. Williamson JW, Goodenough SH, Liberati A, Patterson WB, Lavin P, Zelen M, Setting Priorities for Cancer Control: An Approach, Progress in Clinical and Biological Research, 156:75-86, 1984.

52. Johnson LA, Lavin P, Moertel C, Wieland L Dayal, Y Doos, WG Geller, SA Cooper, HS Nime, F Masse, S Simson, IW Sumner, H Foelsch, E Engstrom, P Carcinoids: The Association of Histologic Growth Pattern and Survival, 1984 Year Book of Cancer, R.L. Clark, R.W. Cumley, R.C. Hickey, editors. Year Book Medical Publishers, Chicago, 229-230, 1985.

53. Engstrom PF, Lavin PT, Douglass HO, Brunner K.W, Postoperative Adjuvant 5-Fluorouracil plus Methyl-CCNU Therapy for Gastric Cancer Patients, Eastern Cooperative Oncology Group Study, Cancer, 55:1868-1873, 1985.

54. Stoll DB, Lavin PT, Engstrom PF, Hematologic Toxicity of Cisplatin and Mitomycin in Combination for Squamous Cell Carcinoma of Esophagus, American Journal of Clinical Oncology, 8:231-234, 1985.

55. Lavin PT, Problems with Tumor Response Criteria, Biology and Treatment of Colorectal Cancer Metastasis, Mastromarino, A.(Ed.), Martinus Nijhoff, Boston, 211-224, 1985.

56. Novis BH, Gluck E Thomas P, Steele GD, Zurawski VR, Stewart R, Lavin PT, Zamcheck N, Serial Levels of CA 19-9 and CEA in Colonic Cancer, Journal of Clinical Oncology, 4, 6:987-993, 1986.

57. Johnson L, Lavin P, Moertel C, et al, Carcinoids: The Prognostic Effect of Primary Site Histologic Type Variations, Primary Site Histoprognostic Type Occurrence Rate Variations, Journal of Surgical Oncology, 33:81-83, 1986.

58. Niloff JM, Knapp RC, Lavin PT, Malkasian GD, Berek JS, Mortel R, Whitney C, The CA 125 Assay as a Predictor of Clinical Recurrence in Epithelial Ovarian Cancer, American Journal of Obstetrics and Gynecology, 155:56-60, 1986.

59. Berek J, Knapp RC, Malkasian G, Lavin PT, et al, CA 125 Serum Levels Correlate with Second Look Operations among Ovarian Cancer Patients, Obstetrics and Gynecology, 67:685-89, 1986.

60. Johnson LA, Lavin PT, Dayal YY, Geller SA, Doos WG, Cooper HS, Gerber JE, Masse ST, Weiland LH, Moertel CG, et al, Gallbladder Adenocarcinoma: Prognostic Significance of Tumor Acid Mucopolysaccharide Content, Journal of Surgical Oncology, 33, 4:243-243, 1986.

61. Lavin PT, A Consultant's View of the Draft Guidelines for the Statistical and Clinical Content of the New Drug Application, American Statistical Association Proceedings, Biopharmaceutical Section, 136-138, 1986.

62. Johnson LA, Lavin PT, Dayal YY, Geller SA, Doos WG, Cooper HS, Gerber JE, Masse SR, Weiland LH, Moertel CG, Engstrom PF, Gallbladder Adenocarcinoma: The Prognostic Significance of Histologic Grade, Journal of Surgical Oncology, 34:16-18, 1987.

63. Lavin P, Knapp RC, Malkasian G, Whitney CW, Berek JC, Bast RC, CA 125 for the Monitoring of Ovarian Carcinoma During Primary Therapy, Obstetrics and Gynecology, 69:223-227, 1987.

64. Kendall K, Mundorf T, Nardin G, Zimmerman TJ, Hesse R, Lavin PT, Tolerability of Timolol and Betaxolol in Patients with Chronic Open Angle Glaucoma, Clinical Therapeutics, 9, 6:651-655, 1987.

65. Osband ME, Lavin PT, Rubin LS, Carpinito GA, Hamilton D, Krane RJ, The Correlation of Survival with Serum Levels of Interleukin-2 Receptor (IL2-R) and Immunosuppressive Acidic Protein (IAP) in Patients with Metastatic Renal Cell Carcinoma Treated with Autolymphocyte Therapy, 1987.

66. Osband M, Panse C, Lavin P. Treatment of Histiocytosis-X with Supressin A. Pediatric Research 21, 4, 1987.

67. Hochberg FH, Lavin PT, Portney R, Roberts D, Tinney C, Hottleman K, Wanger F, Topical Therapy of Localized Inflammation in Musicians: A Clinical Evaluation of Aspercreme versus Placebo, Medical Problems for Performing Artists, 3, 1:9-14, 1988.

68. Kanders BS, Lavin PT, Kowalchuk MB, Greenberg I, Blackburn GL, An Evaluation of the Effect of Aspartame on Weight Loss, Appetite, 11, Supplement, 73-84, 1988.

69. Chandler B, Lavin PT, Efficacy and Tolerability of Enalapril and Its Effect on Serum Lipids in Patients with Mild Uncomplicated Essential Hypertension, Current Therapeutic Research, 43, 6:1143-1149, 1988.

70. Finkler NJ, Benacerraf B, Lavin PT, Wojciechowski C, Knapp RC, Comparison of CA-125, Clinical Impression, and Ultrasound in the Preoperative Evaluation of Ovarian Masses, Obstetrics and Gynecology, 72:659-664, 1988.

71. Malkasian GD Jr, Knapp RC, Lavin PT, Zurawski VR Jr, Podratz KC, Stanhope CR, Mortel R, Berek JS, Bast RC Jr, Ritts RE. Preoperative evaluation of serum CA 125 levels in premenopausal and

postmenopausal patients with pelvic masses: discrimination of benign from malignant disease. Am J Obstet Gynecol. 159(2):341-6, 1988.

72. Weir MR, Krichten C, Urick A, Saunders E, Lavin PT. Comparison of enalapril and hydrochlorothiazide in mild hypertension and changes in plasma lipid concentrations during therapy" Clin Ther. 1988;10(6):712-24.

73. Warner KG, Khuri SF, Marston W, Sharma S, Butler MD, Assousa SN, Saad AJ, Soiuffi,SY, Lavin PT, Significance of the Transdermal Diminution in Regional Hydrogen Ion Production After Repeated Coronary Artery Occlusions, Circulation Research, 64:616-628, 1989.

74. Jenison EL, Montag AG, Griffiths CT, Welch WR, Lavin PT, Greer J, Knapp RC, Clear Cell Adenocarcinoma of the Ovary: A Clinical Analysis and Comparison with Serous Carcinoma, Gynecologic Oncology, 32:65-71, 1989.

75. Blackburn GL, Morgan J, Lavin PT, Noble R, Funderburk F, Istfan N, The Determinants of the Pressor Effect of Phenylpropanolamine in Healthy Subjects, Journal of the American Medical Association, 261:3267-3272, 1989.

76. Blackburn GL, Kanders B, Lavin PT, Norton D, Peterson F, The Improvement of Diabetes, Hypertension and Cardiovascular Conditions in Obese Subjects Following Very Low Calorie Diets, Clinical Nutrition, 1989.

77. Blackburn GL, Wilson GT, Kanders BS, Stein LJ, Lavin PL Adler J, Brownell KD, Weight cycling: the experience of human dieters, Am Jour Clinical Nutrition, 49, 5, 1105-1109, https://doi.org/10.1093/ajcn/49.5.1105

78. Kanders BS, Blackburn GL, Lavin PT, Norton D, Weight Loss Outcome and Health Benefits Associated with the Optifast Program in the Treatment of Obesity. International Journal of Obesity, 2, 13:131-134, 1989.

79. Wolf BC, Salem RR, Sears HF, Horst DA, Lavin PT, Herlyn M, Itzkowitz SH, Scholm J, Steele, GD, Jr, The Expression of Colorectal Carcinoma-Associated Antigens in the Normal Colonic Mucosa. An Immuno-histo-chemical Analysis of Regional Distribution, American Journal of Pathology, 135, 1:111-119, 1989.

80. Blackburn GL, Wilson GT, Kanders BS, Stein LJ, Lavin PT, Adler J, Brownell, KD, Weight Cycling: The Experience of Human Dieters, American Journal of Clinical Nutrition, 49, 5:1105-1109, 1989.

81. Montag AG, Jenison EL, Griffiths C.T, Welch WR, Lavin PT, Knapp RC, Ovarian Clear Cell Carcinoma. A Clinicopathologic Analysis of 44 Cases, International Journal of Gynecological Pathology, 8, 2:85-96, 1989.

82. Warner KG, Khuri SF, Marston W, Sharma S, Butler, MD, Assousa SN, Saad AJ, Siouffi SY, Lavin PT, Significance of the Transmural Diminution in Regional Hydrogenion Production after Repeated Coronary Artery Occlusions, Circulation Research. 64:616-628, 1989.

83. Wells CL, Jechorek RP, Erlandson SL, Lavin PT, Cerra FB, The Effect of Dietary Glutamine and Dietary RNA on Ileal Flora, Ileal Histology, and Bacterial Translocation in Mice, Nutrition, 6, 1:70-75, 1990.

84. Wells CL, Jechorek, RP, Lavin PT, Cerra FB, The Effect of a Uniquely Formulated Diet (Supplemented with Arginine, RNA, and Menhaden Oil) on Ileal Flora, Ileal Histology, and Bacterial Translocation in Mice, Nutrition, 6, 1:76-80, 1990.

85. Osband ME, Lavin PT, Ross S, Krane RJ, A Pilot Study to Evaluate the Safety and Efficacy of Autologous Lymphocyte Therapy in the Treatment of Advanced Metastatic Renal Cell Cancer, Journal of Urology, 1990.

86. Weir MR, Cassidy CA, Hall PS, Lancaster A, Schubert C, Urick A, Saunders E, Kong B.W, Jenkins P, Lavin PT, Efficacy and Tolerability of Enalapril and Sustained-Release Verapamil in Older Patients with Mild to Moderate Essential Hypertension, Clinical Therapeutics, 12, 2:139-148, 1990.

87. Krane RJ, Carpinito GA, Ross SD, Lavin PT, Osband ME, Treatment of Metastatic Renal Cell Carcinoma with Autolymphocyte Therapy. Low Toxicity Outpatient Approach to Adoptive Immunotherapy without Use of in vivo Interleukin-2, Urology, 35, 5:417-422, 1990.

88. Wexler HM, Lavin PT, Molitoris E, Finegold SM, Statistical Analysis of Trial, Reader, and Replicates on MIC Determination for Cefoxitin, Antimicrobial Agents and Chemotherapy, 34, 11:2246-9, 1990.

89. Osband ME, Lavin PT, Babayan RK, Graham S, Lamm DL, Parker B, Sawczuk I, Ross, S, Krane RJ, Effect of Autolymphocyte Therapy on Patients with Advanced Metastatic Renal Cell Carcinoma (see comments), Lancet, 335, 8696:994-998, 1990.

90. Hunter VJ, Weinberg JB, Haney AF, Soper JT, Lavin PT, Metsch L, Knapp RC, Bast RC, Jr., CA 125 in Peritoneal Fluid and Serum from Patients with Benign Gynecologic Conditions and Ovarian Cancer, Gynecologic Oncology, 36:161-165, 1990.

91. Weir MR, Haynie R, Vertes V, Pinson R, Kong BW, Jenkins P. Efficacy and Tolerability of Enalapril and Sustained-Release Diltiazem in Mild to Moderate Essential Hypertension, Clinical Therapeutics, 12, 6:473-481, 1990.

92. Weir MR, Lavin PT, Comparison of the Efficacy and Tolerability of Lisinopril and Sustained-Release Verapamil in Older Patients with Hypertension, Clinical Therapeutics, 13, 3:401-8, 1991.

93. Bank S, Greenberg RE, Magier D, Lavin PT, The Efficacy and Tolerability of Famotidine and Ranitidine on the Healing of Active Duodenal Ulcer and During Six-Month Maintenance Treatment, with Special Reference to NSAID/Aspirin-Related Ulcers, Clinical Therapeutics. 13, 2:304-18, 1991.

94. Weir MR, Kong BW, Jenkins, P, Lavin. PT, Comparison of the Efficacy and Tolerability of Lisinopril and Sustained-Release Verapamil in Black Patients with Hypertension, Clinical Therapeutics, 13, 3:409-16, 1991.

95. Kwasnik EM, Siouffi SY, Lavin PT, Khuri SF, Hemodynamic and Metabolic Responses to Graded Microvascular Occlusion; Journal of Vascular Surgery, 13, 6: 867-74, 1991.

96. Daly JM, Lieberman MD, Goldfine J, Shou J, Weintraub F, Rosato EF, Lavin PT, Enteral Nutrition with Supplemental Arginine, RNA, and Omega-3 Fatty Acids in Post-Operative Patients: Immunologic, Metabolic, and Clinical Outcome, Surgery, 1:56-67, 1992.

97. S Ross, PT Lavin, M Franklin, M Osband. Clinical Outcome in the Treatment of Renal Cell Carcinoma with Autologous Lymphocyte Therapy (ALT) with in Vitro Activated T Cells: Updated Results from a Randomized Clinical Trial. Journal of Immunotherapy 11 (2), 141.

98. Kwolek CJ, Miller A, Stonebridge PA, Lavin PT, Lewis KP, Tannenbaum GA, Gibbons GA, Pomposelli FB, Freeman DV, Campbell DR, LoGerfo FW, Safety of Saline Irrigation for Angioscopy: Results of a Prospective Randomized Trial, Annals of Vascular Surgery, 6:62-68, 1992.

99. Schlain BR, Lavin PT, Hayden CL, Using an Autoregressive Model to Detect Departures from Steady States in Unequally Spaced Tumour Biomarker Data, Statistics in Medicine, 11:515-532, 1992.

100. Lahey SJ, Borlase B, Lavin PT, Levitsky S. Preoperative Risk Factors that Predict Hospital Length of Stay in Coronary Artery Bypass Patients over 60 Years of Age, Circulation Nov, 86 (5 Suppl): II181-5, 1992.

101. McPherson R, Bedard J, Connelly P, Curnew G, Davignon J, Echenberg D, Lavin PT, Leiter L, Lenis J, McQueen M, Montigny M, Munoz C, O'Leary T, Ooi T, Rouleau J-L, Spence D, Tan M, Theroux P. Comparison of the Short-Term Efficacy and Tolerability of Lovastatin and Pravastatin in the Management of Primary Hypercholesterolemia, Clinical Therapeutics, 14, 2:276-290, 1992.

102. Graham S, Babayan RK, Lamm DL, Sawchuk I, Ross SD, Lavin PT Osband ME, Krane RJ. The Use of Ex Vivo Activated Memory T-cells (Autolymphocyte Therapy), in the Treatment of Metastatic Renal Cell Carcinoma: Final Results from a Randomized, Controlled, Multi-Site Study, Seminars in Oncology, 1992.

103. Muto MG, Finkler NJ, Kassis AI, Howes AE, Anderson LL, Lau CC, Zurawski VR, Weadock K, Tumeh SS, Lavin PT Knapp RC. Intraperitoneal Radioimmunotherapy of Refractory Ovarian Carcinoma Utilizing Iodide-131-Labeled Monoclonal Antibody OC 125, Gynecologic Oncology, 45:265-272, 1992.

104. Cady B, Stone MD, McDermott WV, Jenkins RL, Bothe A, Lavin PT, Lovett GJ, Steele GD. Technical and Biological Factors in Disease-Free Survival after Hepatic Resection for Colorectal Cancer Metastastes, Archives of Surgery, 127, 5:561-568, 1992.

105. Bower RH, Lavin PT, LiCari, JJ Jensen, GO VanBuren CT, Cerra FB, Rothkopf MP, Daly JO. A Modified Enteral Formula Reduces Hospital Length of Stay in Patients in Intensive Care Units, Clinical Nutrition, Special Supplement, Vol. 11, 1992.

106. Lavin PT, Maar R, Franklin M, Ross S, Martin J, Osband ME. Autologous Lymphocyte Therapy for Metastatic Renal Cell Carcinoma: Initial Clinical Results from 335 Patients Treated in a Multisite Clinical Practice, Transplantation Proceedings, 24, 6:3057-3062, 1992.

107. Miller A, Marcaccio EJ, Tannenbaum GA, Kwolek CJ, Stonebridge PA, Lavin PT, Gibbons GW, Pomposelli, FB, Freeman, DV, Campbell, DR, LoGerfo, FW. Comparison of Angioscopy and Angiography for Monitoring Infrainguinal Bypass Vein Grafts: Results of a Prospective Randomized Trial, Annals of Vascular Surgery, 6:62-68, 1992.

108. Miller A, Maracaccio EJ, Tannenbaum GA, Kwolek CJ, Stonebridge PA, Lavin PT, Gibbons GW, Pomposelli FB, Jr, Freeman DV, Campbell DR, et al, Comparison of angioscopy and angiography for monitoring infrainguinal bypass vein grafts: result of a prospective randomized trial. J Vasc. Surg, Feb;17(2):382-96; discussion 396-8. 1993.

109. Weir MR, Lavin PT, Comparison of the efficacy and tolerability of Prinivil and Procardia XL in black and white hypertensive patients. Clin. Ther, Sep-Oct: 14(5):730-9. 1992.

110. Schlain BR, Lavin PT, Hayden CL, Using Autoregressive and Random Walk Models to Detect Trends and Shifts in Unequally Spaced Tumour Biomarker Data, Statistics in Medicine, 12:265-279, 1993.

111. Graham S, Babayan RK, Lamm DL, Sawczuk I, Ross SD, Lavin PT, Osband ME, Krane RJ.. The use of ex vivo-activated memory T cells (autolymphocyte therapy) in the treatment of metastic renal cell carcinoma: final results from a randomized, controlled, multisite study. Semin Urol, Feb;11(1):27-34. 1993.

112. Kanders BS, Blackburn GL, Lavin PT. The longterm effect of aspartame on body weight among obese women. Obesity in Europe, 1993.

113. Weir MR, Lavin PT, Byrnes CA. Efficacy and tolerability of a combination of enalapril and hydrochlorothiazide in the treatment of hypertension measured manually and with an ambulatory blood pressure monitor. Clin. Ther. May-June;15(3):527-38. 1993.

114. Marcaccio EJ, Miller A, Tannenbaum GA, Lavin PT, Gibbons GW, Pomposelli FB, Freeman DV, Campbell DR, LoGerfo FW. Angioscopically directed interventions improve arm vein bypass grafts. J Vasc. Surg. June;17 (6):994-1002; discussion 1003-4. 1993.

115. Salem RR, Wolfe BC, Sears HF, Lavin PT, Ravikumar TS, DeCoste D, Emilia JC, Herlyn M, Schlom J, Gottlieb LS, Steele GD. Expression of Colorectal Carcinoma Associated Antigens in Colonic Polyps, Journal of Surgical Research, Sep; 55 (3):249-55, 1993.

116. Young BK, Ehrmann RL, Dean B, Knapp RC, Lavin PT, Niloff JM. Analysis of Pap Smear Screening Failure in Patients Presenting with Cervical Carcinoma, July- September, 11, 3:114-117, 1993.

117. Bank S, Blumstein M, Greenberg RE, Magier D, Lavin PT. Efficacy of famotidine in the healing of active benign gastric ulceration: comparison of nonsteroidal anti-inflammatory or aspirin-induced gastric ulcers idiopathic gastric ulceration. Long Island Jewish Medical Center Acid-Peptide Group. Clin Ther. Jan-Feb; 15(1): 36-45, 1993.

118. Krane RJ, Ross SD, Babbitt B, Lavin PT, Martin J, Goodwin J, Caplan B, Zhang J, Osband ME. The scientific and clinical results of ex vivo activated T cells for metastatic renal cell carcinoma in over 500 human patients. Cell Transplant 3; Suppl 1:S51, 1994.

119. Salvon-Harmon JC, Cady B, Nikulasson S, Khettry U, Stone MD, Lavin PT. Shifting proportions of gastric adenocarcinomas. Arch Surg, Apr;129(4):381-8; discussion 388-9, 1994.

120. Hölzenbein, TJ, Miller A, Tannenbaum GA, Contreras MA, Lavin PT, Gibbons GW, Campbell DR, Freeman DV, Pomposelli FB, LoGerfo FW. Role of Angioscopy in Reoperation for the Failing or Failed Infrainguinal Vein Bypass Graft, Annals of Vascular Surgery, 8, 1:74-91, 1994.

121. Lavin PT, Sanders PG, Mackey MA, Kotsonis FN. Intense Sweeteners Use and Weight Change Among Women: A Critique of the Stellman and Garfinkel Study, Journal of the American College of Nutrition, 13, 1:102-105, 1994.

122. Kanders BS, Peterson FJ, Lavin PT, Norton DE, Istfan NW, Blackburn GL. A Long-Term Health Effects Associated with Significant Weight Loss: A Study of the Dose-Response Effect, Obesity: Pathophysiology, Psychology and Treatment, GL. Blackburn, Kanders (Eds) Chapman & Hall, Inc, 167-184, 1994.

123. Blackburn GL, Kanders BS, Lavin PT. Dietary intervention to reduce body weight in obese individuals: the usefulness of aspartame. APJCN: 4, 3:327, 1995.

124. Schwartz B, Takamoto T, Lavin PT. An Increase of Retinal Vessel Width in Ocular Hypertensives with Timolol Therapy, Acta Ophthalmologica Scandanavica 1995, 73 (Suppl 215): 41-53, 1995.

125. Amoroso PJ, Dettori, JR, Reynolds KL, Schneider GA, Lavin PT. Tobacco Use and Injury Risk Among Military Parachutists, Army Research Institute of Environmental Medicine, Natick, MA 06 MAR 1995

126. Schwartz B, Takamoto T, Lavin PT. An Increase of Retinal Nerve Fiber Layer Thickness in Ocular Hypertensives with Timolol Therapy, Acta Opthalmologica Scandanavica 1995, 73 (Suppl 215): 22-32, 1995.

127. Schwartz B, Lavin PT, Takamoto T, Araujo DF, Smits G, A Decrease of Optic Disc Cupping and Pallor of Ocular Hypertensives with Timilol Therapy, Acta Opthalmologica Scandanavica 1995, 73 (Suppl 215): 5-21, 1995.

128. Jessup JM, Lavin PT, Andrews CW, Loda M, Mercurio A, Minsky B, Mies C, Bleday R, Steele G. Sucrase-Isomaltase is an independent prognostic marker for human colorectal carcinoma. Dis Colon Rect. 38:1257-64, 1995.

129. Kanders BS, Blackburn GL, Lavin PT, Evaluation of Weight Control, in The Clinical Evaluation of a Food Additive: Assessment of Aspartame, edited by C Tschantz, H Butchko, WW Stargel, F Kotsonis, CRC Press, Boca Raton, FL, 289-299, 1996.

130. Shibata D, Reale MA, Lavin P, Silverman M, Fearon ER, Steele G, Jr, Jessup J, Loda M, Summerhayes IC, Loss of DCC Expression and Prognosis in Colorectal Cancer, N. Engl. J. Med, 335: 1727-32, 1996.

131. Cady B, Stone MD, Schuler JG, Thakur R, Wanner MA, Lavin PT. The new era in breast cancer. Invasion, size, and nodal involvement dramatically decreasing as a result of mammographic screening. Arch Surg, Mar;131(3):301-8, 1996.

132. Klicka MV, King N, Lavin PT, Askew EW. Assessment of dietary intakes of cadets at the US Military Academy at West Point. J Am Coll Nutr. 15(3):273-82, 1996.

133. Loda M, Cukor B, Tam S, Lavin P, Fiorentino M, Draetta GF, Jessup JM, Pagano M, Increased Proteasome-dependent Degradation of the Cyclin-dependent Kinase Inhibitor p27 in Aggressive Colorectal Carcinoma, Nature Med; 3, 231-234, 1997. (Editorial in the same issue).

134. Tan P, Cady B, Wanner M, Worland P, Cukor B, Magi-Galluzzi C, Lavin P, Pagano M, Loda M, The Cell Cycle Inhibitor p27 is an Independent Prognostic Marker in Small (T1a,b) Invasive Breast Carcinomas, Cancer Res, 57:1259-1263, 1997.

135. Miller A, Holzenbein TJ, Gottlieb MN, Sacks BA, Lavin PT, Goodman WS, Gupta SK. Strategies to increase the use of autogenous arteriovenous fistula in end-stage renal disease. Ann Vasc Surg. 11(4):397-405, July 1997.

136. Lise M, Loda M, Fiorentino M, Mercurio AM, Summerhayes IC, Lavin PT, Jessup JM, Association between Sucrase-Isomaltase (SI) and p53 Expression in Colorectal Cancer, Annals Surg Oncol, Am Journ of Path, 4:176-83, 1997.

137. Fogt F, Nikulasson S, Holden JA, Alder SA, Hallgrimsson J, Jessup MJ, O'Brien MJ, Lavin PT, Goldman H, Topoisomerase II. Alpha Expression in Normal, Inflammatory and Neoplastic Conditions of the Gastric and Colonic Mucosa, Mod Pathol, Apr: 10 (4): 296-302. 1997.

138. Blackburn GL, Kanders B, Lavin PT, Whatley J, Keller SA, The Effect of Aspartame as Part of a Multidisciplinary Weight Control Program on Short- and Long-term Control of Body Weight, Am Journ Clin Nutr, Feb: 65(2):409-18, 1997.

139. Cady B, Jenkins RL, Steele GD, Jr., Lewis W D, Stone MD, McDermott WV, Jessup JM, Botha A, Lalor P, Lovett EJ, Lavin PT, Linehan DC. Surgical Margin in Hepatic Resection for Colorectal Cancer, Annals of Surgery. 227, 4:566 –571. 1998.

140. Kobelin MH, Kobelin CG, Burke L, Lavin PT, Niloff JM, Kim YB. Incidence and predictors of cervical dysplasia in patients with minimally abnormal Papanicolaou smears. Obstet Gynecol. 92(3):356-9, Sept 1998.

141. Forshee JD, Whalen EB, Hackel R, Butt LT, Smeltzer PA, Martin J, Lavin PT, Buchner DA. The effectiveness of one-on-one nurse education on the outcomes of high-risk adult and pediatric patients with asthma. Manag Care Interface, 1998 Dec;11(12):82-92.

142. Sigal LH, Zahradnik JM, Lavin P, Patella SJ, Bryant G, Haselby R, Hilton E, Kunkel M, Adler-Klein D, Doherty T, Evans J, Molloy PJ, Seidner AL, Sabetta JR, Simon HJ, Klempner MS, Mays J, Marks D, Malawista SE. A vaccine consisting of recombinant Borrelia burgdorferi outer-surface protein A to prevent Lyme disease. Recombinant Outer-Surface Protein: A Lyme Disease Vaccine Study Consortium. N Engl J Med. 1998 Jul 23;339(4):216-22.

143. AH Dachman, JK Kuniyoshi, CM Boyle, Y Samara, KR Hoffmann, P Lavin. CT colonography with three-dimensional problem solving for detection of colonic polyps. American Journal of Roentgenology 1998. 171 (4), 989-995

144. Taylor JA, Goluboff ET, Holub W, Krane RJ, Fawwaz R, Codington JF, Maimonis P, Lavin PT, Olsson CA. The Human Carcinoma Antigen: A New Biomarker for Prostate Cancer. Jour Urol 161 (4S). 1999.

145. Chopra A, Lavin P, Patwardhan B, Chitre D. Randomized double blind trial of an ayurvedic plant derived formulation for treatment of rheumatoid arthritis. J Rheumatol June 2000(6): 1365-72.

146. Pusateri T, Lavin P, Baldy C, Copland K, Sequiti M. Impact of Variable Tint Optics (Transitions® Gray) on Vision-related Quality of Life in Normal Volunteers: A Randomized Clinical Comparison in a Warm Climate. The CLAO Journal, October 2000: Vol. 26, No. 4.

147. Brandt KD, Block JA, Michalski JP, Moreland LW, Caldwell JR, Lavin PT. Efficacy and safety of intraarticular sodium hyaluronate in knee osteoarthritis. ORTHOVISC Study Group. Clin Orthop. (385):130-43, Apr 2001.

148. Dearani JA, Axford TC, Patel MA, Healey NA, Lavin PT, Khuri SF. Role of myocardial temperature measurement in monitoring the adequacy of myocardial protection during cardiac surgery. Ann. Thorac. Surg. 72: 2235S-2243S. 2001

149. Katz-Brull R, Lavin PT, Lenkinski RE. Clinical Utility of Proton Magnetic Resonance Spectroscopy in Characterizing Breast Lesions. Jnl. of Nat'l Cancer Inst. 94(6): 1197-1203, Aug 2002.

150. Reilly MC, Lavin PT, Kahler KH, Pariser DM. Validation of the Dermatology Life Quality Index (DLQI) and the Work Productivity and Activity Impairment: Chronic Hand Dermatitis Questionnaire (WPAI-ChHD) in Chronic Hand Dermatitis (ChHD), J Am Acad Dermatol 48:128-30, 2003.

151. Sosna J, Morrin MM, Kruskal JB, Lavin PT, Rosen MP, Raptopoulos V. CT Colonography of Colorectal Polyps: A Meta Analysis, AJR Am J Roentgenol. 181(6):1593-8, Dec 2003.

152. S. Gaston, M. Soares, M. Minhaj Siddiqui, D. Vu, M. Brice, J. Shih, M. Upton, G. Perides, J. Baptista, P. Lavin, Mapping molecular markers in prostate cancer: Profiling tumor invasion of the prostate capsule and positive surgical margins. European Urology Supplements, 2, 6, 99, 2003.

153. Carr DB, Goudas LC, Denman WT, Brookoff D, Staats PS, Brennen L, Green G, Albin R, Hamilton D, Rogers MC, Firestone L, Lavin PT, Mermelstein F. Safety and efficacy of intranasal ketamine for the treatment of breakthrough pain in patients with chronic pain: a randomized double-blind, placebo-controlled, crossover study. Pain 108, 17-27, 2004.

154. Gaston SA, Soares MA, Siddiqui MM, Vu D, Lee JM, Goldner DL, Brice MJ, Shih JC, Upton MP, Perides G, Baptista J, Lavin PT, Bloch BN, Genega EM, Rubin MA, Lenkinski RE. Tissue-print and print-phoresis as platform technologies for the molecular analysis of human surgical specimens: mapping tumor invasion of the prostate capsule. Nature Medicine 11, 95-101, 2004.

155. Demetriou AA, Brown RS Jr., Busuttil RW, Fair J, McGuire BM, Rosenthal P, Am Esch JS 2nd, Lerut J, Nyberg SL, Salizzoni M, Fagan EA. de Hemptinne B, Broelsch CE, Muraca M, Salmeron JM, Rabkin JM, Metselaar HJ, Pratt D, De La Mata M, McChesney LP, Everson GT, Lavin PT, Stevens AC, Pitkin Z, Solomon BA. Prospective, randomized, multicenter, controlled trial of a bioartificial liver in treating acute liver failure. Annals of Surgery 239: 660-7, 2004.

156. Chopra A, Lavin P, Bhushan P, Deepa C. A 32-week randomized, placebo-controlled clinical evaluation of RA-11, an Ayurvedic drug, on osteoarthritis of the knees, Journal of Clinical Rheumatology 10, 5, 236—245, 2004.

157. Kacmarek RM, Wiedemann HP, Lavin PT, Wedel MK, Tutuncu AS, and Slutsky AS. Partial Liquid Ventilation in Adult Patients with the Acute Respiratory Distress Syndrome, Am. J. Respir. Crit. Care Med. doi:10.1164/rccm.200508-1196OC, 2005.

158. Nevins M, Giannobile WV, McGuire MK, Kao RT, Mellonig JT, Hinrichs JE, McAllister BS, Murphy KS, McClain PK, Nevins ML, Paquette DW, Han TJ, Reddy MS, Lavin PT, Genco RJ, and Lynch SE. Platelet-Derived Growth Factor Stimulates Bone Fill and Rate of Attachment Level Gain: Results of a Large Multicenter Randomized Controlled Trial, Journal of Periodontology, 76, 12, 2205-2215, 2005.

159. Lynch SE, Lavin PT, Genco RJ, Beasley WG, Wisner-Lynch LA. New Composite Endpoints to Assess Efficacy in Periodontal Therapy Clinical Trials, Journal of Periodontology, 77, 8: 1314-1322, Aug 2006.

160. Ramanathan R, Saunders W, Lavin P, Sekar K, Ernst , Bhatia J.. Mortality Differences among Pre-term Infants Treated with Three Different Surfactants: Analyses rom a Large National Database. Journal of Perinatology 27 (10), 2007.

161. Sekar S, Bhatia J, Ernst F, Saunders W, Lavin PT, Ramanathan R. Resource use in pre term neonates with respiratory distress syndrome (RDS) treated with one of three different natural surfactants: analyses using a large hospital discharge. Acta Paediatrica 96, 2007.

162. Lavin, Philip T., Meta-Analysis Combining 2 Previously Reported Trials on Respiratory Distress Syndrome in Neonates, Pediatrics 120, 5, 1223-1224, Nov 2007.

163. Mitchel JT, Kim YJ, Choi J, Tantsyura V, Nadler D, Grimes I, Cappi S, Lavin PT, Mousley K. The Impact of Electronic Data Capture on Clinical Data Management, Monitor, August 2008.

164. Lodge AJ, Wells WJ, Backer CL, O'Brien JE, Austin EH, Bacha EA, Yeh T, DeCampli WM, Lavin PT, Weinstein S. A Novel Bioresorbable Film Reduces Postoperative Adhesions After Infant Cardiac Surgery, Ann Thorac Surgery, 86:614-21, 2008.

165. McGuire MK, Scheyer ET, Nunn ME, Lavin PT. A Pilot Study to Evaluate a Tissue-Engineered Bilayered Cell Therapy as an Alternative to Tissue from the Palate. J Periodontol. 79(10):1847-56, Oct 2008.

166. Weiss, RA, Lavin, PT, Reduction of Pain and Anxiety Prior to Botulinum Toxin Injections with a New Topical Anesthetic Method, Ophthalmic Plastic & Reconstructive Surgery. 25(3): 173-177, May/June 2009.

167. Carr D, Goudas L, Denman W, Brookoff D, Lavin P, Staats P. Safety and efficacy of intranasal ketamine in a mixed population with chronic pain. Pain, 110, 3, 762-764, 2010.

168. Ottoman C, Hartmann B, Schaden W, Stojadinovic A, Lavin P. Prospective randomized trial of accelerated re-epithelialization of skin donor sites using extracorporeal shock wave therapy. J Am Coll Surg 211, 4, 568-569, 2010.

169. Maki DG, Ash SR, Winger RK, Lavin PT. A novel antimicrobial and antithrombotic lock solution for hemodynamic catheters: A multi-center, controlled randomized trial, Critical Care Medicine, 39, 4, 613-620, 2011.

170. Menon S, Massaro J, Lewis J, Pencina M, Wang YC, Lavin P. Sample size calculation for Poisson endpoints using exact distribution of difference between two Poisson random variables. Stat Biopharm Res. 2011.

171. Ottomann C, Stojadinovic A, Lavin P, Gannon F, Heggeness MH, Thiele R, Schaden W, Hartmann B. Prospective randomized Phase II trial of accelerated re-epithelialization of superficial second degree burn wounds using extracorporeal shock wave therapy. Annal Surg 2011.

172. Strand V, Baraf HSB, Lavin P, Lim S, Hosokawa H. A multi-center, randomized, controlled trial comparing a single intra-articular joint injection of Gel-200, a new cross-linked formulation of hyaluronic acid, to phosphate buffered saline for treatment of osteo-arthritis of the knee. Osteo Cart. 20, 350-356, 2012.

173. Strand V, Baraf HSB, Lavin P. An extension study to evaluate continued effectiveness and safety of

repeat single intra-articular joint injection of Gel-200 for treatment of osteo-arthritis of the knee. Osteo Cart. 21, 32-41, 2012.

174. Ash S, Singh B, Lavin P, Stavros F, Rasmussen H. Safety and Efficacy of ZS-9, a novel selective cation trap, for treatment of hyperkalemia in CKD patients. Journal of the American Society of Nephrology: JASN, 24: 1061, 2013.

175. Imperiale TF, Ransohoff DF, Itzkowitz SH, Levin TR, Lavin PT, Lidgard GP, Alquist DA, Berger BM. Multi-target Stool DNA Testing for Colorectal-Cancer Screening. N Engl J Med. 370, 287-297, 2014.

176. Packham DK, Rasmussen HS, Lavin PT, et al. Sodium zirconium cyclosilicate in hyperkalemia. N Engl J Med. 2014. DOI: 10.1056.

177. Kosiborod M, Rasmussen HS, Lavin P, et al. Effect of sodium zirconium cyclosilicate on potassium lowering for 28 days among outpatients with hyperkalemia: the HARMONIZE randomized clinical trial. JAMA 17 Nov 2014. doi:10.1001/jama.2014.15688.

178. Ash SR, Singh B, Lavin PT, Stavros F, Rasmussen HS. A phase 2 study on the treatment of hyperkalemia in patients with chronic kidney disease suggests that the selective potassium trap, ZS-9, is safe and efficient, Kidney International 4 Feb 2015; doi: 10.1038/ki.2014.382.

179. Anker SD, Kosiborod M, Zannad F, Piña IL, McCullough PA, Filippatos G, Van der Meer P, Ponikowski P, Rasmussen HS, Lavin PT, Singh B, Yang A, Prakash Deedwania P. Maintenance of serum potassium with sodium zirconium cyclosilicate (ZS-9) in heart failure patients: Results from a phase 3 randomized, double-blind, placebo-controlled trial. European Journal of Heart Failure. 2015 doi:10.1002/ejhf.300.

180. Zalev J, Clingman B, Herzog D, Miller T, Ulissey M, Stavros AT, Oraevsky A, Lavin P, Kist K, Dornbluth NC, Otto P. Opto-acoustic image fusion technology for diagnostic breast imaging in a feasibility study. Proc. SPIE 9419, Medical Imaging 2015: Ultrasonic Imaging and Tomography, 941909. 17 March 2015.

181. Doros G, Lavin PT, Daley M, Miller LE. A method for establishing class III medical device equivalence: sodium hyaluronate (GenVisc 850) for the treatment of knee osteoarthritis. Med Devices (Auckl). 2016 Jul 13;9:205-11. doi: 10.2147/MDER.S104327. eCollection.

182. Jalal SI, Lavin P, Lo G, Lebel F, Einhorn L. Carboplatin and Etoposide With or Without Palifosfamide in Untreated Extensive-Stage Small-Cell Lung Cancer: A Multicenter, Adaptive, Randomized Phase III Study (MATISSE). 2017:35 23 2619-2623.

183. Cholkeri-Singh A, Lavin PT, Olson CG, Papagiannakis E, Weinberg L. Digital Colposcopy with Dynamic Spectral Imaging for Detection of Cervical Intraepithelial Neoplasia 2+ in Low-Grade Referrals: The IMPROVE-COLPO Study. Journal of Lower Genital Tract Disease: 2017 Sept 25; doi: 10.1097/LGT.0000000000000353.

184. DeNardis SA, Lavin PT, Livingston J, Salter WR, Nanette James-Patrick N, Papagiannakis E, Olson CG, Weinberg L. Increased detection of precancerous cervical lesions with adjunctive dynamic spectral imaging. International Journal of Women's Health. International Journal of Women's Health 2017:9 717–725.

185. Neuschler EI, Butler R, Young CA, Barke LD, Bertrand ML, Böhm-Vélez M, Destounis M, Donlan P,

Grobmyer SR, Katzen J, Kist KA, Lavin PT, Makariou EV, Parris TM, Schilling KJ, Tucker FL, Dogan BE. A pivotal study of optoacoustic imaging to diagnose benign and malignant breast masses: A new evaluation tool for radiologists. Radiology 2018 05 27;287(2):398-412.

186. Menezes GLG, Pijnappel RM, Meeuwis C, Bisschops R, Veltman J, Lavin PT, Van De Vijver MJ, Mann RM. Downgrading of Breast Masses Suspicious for Cancer by Using Optoacoustic Breast Imaging. Radiology 2018 288: 2 355-365.

187. Abràmoff, MD, Lavin, PT, Birch, M, Shah, N, and Folk, JC. Pivotal trial of an autonomous AI-based diagnostic system for detection of diabetic retinopathy in primary care offices. npj Digital Med. 39. 2018.

188. Neuschler EI., Lavin PT, Tucker FL, Barke LD, Bertrand ML, Bohm-Valez M, Destounis S, Dogan BE, Grobmyer ST, Katzen J, Kist KA, Makariou EV, Parris TM, Young CA, Butler R. Downgrading and Upgrading Gray-Scale Ultrasound BI-RADS Categories of Benign and Malignant Breast Masses with Opto-acoustics – A Pilot Study Am J Roentgenology. 211, 689-700, 2018.

189. Butler R, Lavin PT, Tucker FL, Barke LD, Bohm-Valez M, Destounis S, Grobmyer SR, Katzen J, Kist KA, Makariou EV, Schilling KJ, Young CA, Dogam BE, Neuschler EI. Opto-Acoustic Breast Imaging-Imaging-Pathology Correlation of Opto-Acoustic Features in Benign and Malignant Breast Masses. Am J Roentgenology. 211:1–16, 2018.

190. Myer GD, Barber Foss K, Thomas S, Galloway R, DiCesare CA, Dudley J, Gadd B, Leach J, Smith D, Gubanich P, Meehan WP, Altaye M, Lavin P, Yuan W. Altered Brain Microstructure in Association with Repetitive Sub-concussive Head Impacts and the Potential Protective Effect of Jugular Vein Compression: A Longitudinal Study of Female Soccer Athletes. Br J Sports Med 53:1–14. doi:10.1136/bjsports-2018-099571, 2018.

191. Spinowitz BS, Fishbane S, Pergola PE, Roger SD, Lerma EV, Butler J, von Haehling S, Adler SH, Zhao J, Singh B, Lavin PT, McCullough PA, Kosiborod M, Packham DK on behalf of the ZS-005 Study Investigators Sodium Zirconium Cyclosilicate among Individuals with Hyperkalemia CJASN CJN.12651018; DOI: https://doi.org/10.2215/CJN.12651018. May 2019.

192. Reetz K, Hilgers R-D, Isfort S, Dohmen M, Didszun C, Fedosov K, Kistermann J, Mariotti C, Durr A, Boesch S, Klopstock T, Francisco de Rivera Garrido JR, Schöls L, Klockgether T, Pandolfo M, Korinthenberg R, Lavin P, Molenberghs G, Libri V, Giunti P, Festenstein R, Jörg B. Schulz & the EFACTS or NICOFA Study Group. Protocol of a randomized, double-blind, placebo-controlled, parallel-group, multicentre study of the efficacy and safety of nicotinamide in patients with Friedreich ataxia (NICOFA). Neurol. Res. Pract. 1, 33 (2019). https://doi.org/10.1186/s42466-019-0038-9.

193. Menezes GLG, Mann RM, Meeuwis C, Bisschops R, Veltman J, Lavin PT, van de Vijver MJ, Pijnappel RM. Optoacoustic imaging of the breast: correlation with histopathology and histopathologic biomarkers. European Radiology. https://doi.org/10.1007/s00330-019-06262-0. May 2019.

194. Roger SD, Lavin PT, Lerma EV, McCullough PA, Butler J, Spinowitz BS, von Haehling S, Kosiborod M, Zhao J, Fishbane S, Packham DK. Long-term safety and efficacy of sodium zirconium cyclosilicate for hyperkalaemia in patients with mild/moderate versus severe/end-stage chronic kidney disease: comparative results from an open-label, Phase 3 study, Nephrology Dialysis Transplantation, 2019, gfz285, https://doi.org/10.1093/ndt/gfz285

195. Weiser E, Parks PD, Swartz RK, Van Thomme J, Lavin PT, Limburg P, Berger BM. Cross-sectional

adherence with the multi-target stool DNA test for colorectal cancer screening: Real-world data from a large cohort of older adults. Jour Med Scr. https://doi.org/10.1177/0969141320903756 Feb 2020

196. Edmiston CE, Lavin PT, Spencer M, Borlaug G. Antiseptic Efficacy of an Innovative Perioperative Surgical Skin Preparation: A Confirmatory FDA Phase 3 Analysis DOI: https://doi.org/10.1017/ice.2020.27 Cambridge University Press: 05 March 2020

197. Syage JA, Lavin PT. Modeling Symptom Severity and Estimated Gluten Ingestion in Celiac Disease Patients on a Gluten-Free Diet. Int Jour Celiac Dis 2020, 8, 3, 85-89. http://pubs.sciepub.com/ijcd/8/3/3, DOI:10.12691/ijcd-8-3-3

198. Harris KE, Lavin PT, Akin MD, Papagiannakis E, Denardis S, Rate of detecting CIN3+ among patients with ASC-US using digital colposcopy and dynamic spectral imaging. Oncology Letters. 20, 4 October 2020. https://doi.org/10.3892/ol.2020.11878.

199. Di Bisceglie AM, Watts GF, Lavin P, Yu M, Bai R, Liu L. Pharmacokinetics and pharmacodynamics of HTD1801 (berberine ursodeoxycholate, BUDCA) in patients with hyperlipidemia. Lipids in Health and Disease. 19:239 2020 https://doi.org/10.1186/s12944-020-01406-4.

200. Youssef JG, Javitt JC, Lavin PT, Mukhtar Al-Saadi M, Zahiruddin F, Beshay S, Bittar MZ, Kelly JA, Mohi Sayed MU. VIP in the Treatment of Critical Covid-19 with Respiratory Failure in Patients with Severe Comorbidity: A Prospective Externally Controlled Trial. J Infect Dist. 2021; 7, 8, 52, 1-10.

201. Fiala T, Lavin P. Safety of a 1064-nm robotic laser system for noninvasive lipolysis of the flanks. Lasers in Surgery and Medicine. CLINICAL REPORTS. 9 March 2022 https://doi.org/10.1002/lsm.23532.

202. Murray JA, Syage JA, Wu T-T, Dickason MA, Ramos AG, Van Dyke C, Horwath I, Lavin PT, Mäki M, Hujoel I, Papadakis KA, Bledsoe AC, Khosla C, Sealey-Voyksner JA. Latiglutenase Protects the Mucosa and Attenuates Symptom Severity in Patients with Celiac Disease Exposed to a Gluten Challenge, Gastroenterology, August 2, 2022 DOI:https://doi.org/10.1053/j.gastro.2022.07.071

203. Youssef JG, Lavin P, Schoenfeld DA. Lee RA, Lenhardt R, Park DJ, Fernandez JP, Morganroth ML, Javitt JC, Jayaweera D. The Use of IV Vasoactive Intestinal Peptide (Aviptadil) in Patients With Critical COVID-19 Respiratory Failure: Results of a 60-Day Randomized Controlled Trial. Critical Care Medicine: August 31, 2022 10.1097/CCM.0000000000005660 doi: 10.1097/ CCM.0000000000005660

204. Seiler SJ, Neuschler EI, Butler RS, Lavin PT, Dogan BE. Optoacoustic Imaging With Decision Support for Differentiation of Benign and Malignant Breast Masses: A 15-Reader Retrospective Study. AJR 2022 Dec 7 [published online]. Accepted manuscript. doi:10.2214/AJR.22.28470

205. Banwari A, Cañizares RB, Saliba F, Ballester MP, Tomescu DR, Martin D, Stadlbauer V, Wright G, Sheikh M, Morgan C, Alzola C, Lavin P, Green D, Kumar R, Sacleux SC, Schilcher G, Koball S, Tudor A, Minten J, Domenech G, Aragones JJ, Oettl K, Paar M, Waterstradt K, Bode-Boger SM, Ibáñez-Samaniego L, Gander A, Ramos C, Chivu A, Stange J, Lamprecht G, Sanchez M, Mookerjee RP, Davenport A, Davies N, Pavesi M, Andreola F, Albillos A, Cordingley J, Schmidt H, Carbonell-Asins JA, Arroyo V, Fernandez J, Mitzner S, Jalan R. Randomized, controlled clinical trial of the DIALIVE liver dialysis device versus standard of care in patients with acute- on- chronic liver failure. Journal of Hepatology 2023. 1–14.

206. Imperiale TF, Porter K, Zella J, Gagrat ZD, Olson MC, Statz S, Garces J, Lavin PT, Aguilar H, Brinberg D, Berkelhammer C, Kisiel JB, and Limburg PJ. Next-Generation Multitarget Stool DNA Test for Colorectal Cancer Screening. N Engl J Med 2024; 390:984-93. DOI: 10.1056/NEJMoa2310336

CHAPTERS

1. Williams RM, Kraus LJ, Lavin PT, Steele LL. "Genetics of Survival in Mice; Localization of Dominant Effects to Subregions of the Major Histocompatability Complex," Proceedings of NIH Conference on Immunology and Aging, Vol. 15, edited by D. Sergre and L. Smith, Marcel Dekker, 247-254, 1981.

2. Louis T, Shapiro S. Clinical Trials: Issues and Approaches, Edited by Stanley H. Shapiro and Thomas A. Louis. pp. 209 + x. New York: Marcel Dekker, 1983.

3. Gelber R, Lavin P, Mehta C, Schoenfeld D. "Statistical Methods of Aquatic Toxicology," In Fundamentals of Aquatic Toxicology, Rand, GM, Petrocelli, SR. (Eds.), Hemisphere Publishing, New York City, 110-123, 1984.

4. Lavin PT, Osband ME. "Evaluating the Role of Therapy in Histiocytosis-X Clinical Studies, Staging, and Scoring" Histiocytosis-X, Hematology/Oncology Clinics of N. America, 1, 1, WB Saunders, 1987.

5. Lavin PT. "Statistical Issues in the Design and Analysis of Clinical Studies," Gynecologic Oncology, RC Knapp RS Berkowitz (Eds.), McGraw-Hill Publishing Company, 150-175, 1992.

6. Kanders BS, Blackburn GL, Lavin PT. The long-term effect of aspartame on body weight among obese women. Obesity in Europe. Edited: Ditschuneit H, Gries FA, Hauner H, Schusdziarra, Wechsler, John Libbey & Company, London, Paris, Rome, 1994.